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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,745	04/09/2004	Michael Snyder	1030.004	1863

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,745	SNYDER ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 07/29/2008.

Claims 1-10 and 12-20 have been canceled. Claims 21- 24 have been added.

Claims 11 and 21-24 are pending and included in the prosecution.

The following new grounds of rejections are necessitated by applicants' amendment:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 11 and 21-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended claim 11 and the newly added claims 21-24 introduced new matter. The following limitations are not described in the specification as originally filed: "flow passage between a first end located in a first

portion of an eye and a second end located in a second portion of the eye" and "other mass under consideration". Nowhere in the specification had applicants disclosed tube between two portion of the eye, or mass. In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 22, the claim recites the limitation "the wound" in second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 24, the claim recites the limitation "the layer" in second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 11, 21, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,360,399 ('399) combined with US 6,074,661 ('661).

The present claim 11 is directed to implant for glaucoma drainage having lumen and having openings in the wall and in its lumen comprises composition comprising caprolactone and antimicrobial agent. The lumen is circular and the sustained release material is solid.

US 399 teaches glaucoma drainage tube that is made of plastic and contains orifices of fixed sizes and shapes (abstract; col.2, lines 4-9; col.3, lines 45-57; col.4, lines 65-67). Figure 4 shows that lumen is circular and has fixed inner and outer dimensions. The tube has lumen containing composition to deliver active agent that escape through the orifices (col.5, lines 21-40; col.4, lines 20-25).

US '399 does not teach the active agent delivered from sustained release medium that comprises caprolactone and antimicrobial agent as instantly claimed by claim 11.

US '661 teaches ocular implant to deliver active agent into the eye comprises antimicrobial agent and bioerodible polymer such as caprolactone providing sustained release of the active agent (col.2, lines 14-21; col.4, lines 40-50, 61-65). US '661 desired to protect the sustained release polymer formulation from erosion, disintegration or fragmentation of the implant by effect of ocular tissue, and in order to accomplish this desire, the surface was altered by coating the implant with another biodegradable semipermeable polymer, or the addition of another polymer to the blend (col.5, lines 5-13). Therefore, protection of the sustained release polymer such as caprolactone containing active agent was desired by US '661.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide implant comprising glaucoma drainage plastic tube having orifices and contain medium to deliver active agent to the surrounding tissue as disclosed by US '399, and replace the medium containing the active agent with the erodible polymer formulation comprising caprolactone and active agent disclosed by US '661 because US '661 teaches that such formulation provides sustained release of the active agent, as desired by applicants, and further one having ordinary skill in the art would have been motivated to do so because US '661 desired to protect the erodible polymeric sustained release formulation from disintegration or fragmentation by effect of ocular tissue and one having ordinary skill in the art would have been motivated to

protect the sustained released formulation of US '661 inside the glaucoma drainage tube of US '299, with reasonable expectation of having implant comprising glaucoma drainage plastic tube having orifices containing sustained release bioerodible formulation comprising caprolactone and active agent that deliver the active agent in a sustained release manner without being disintegrated by the ocular tissue.

Regarding the limitation of increase of the degree of opening of the head space passage (claim 11), the combined teaching of US '399 and US '661 provides glaucoma drainage tube having lumen filled with polymer composition comprising bioerodible caprolactone, and it is expected that caprolactone will be eroded forming the head space passage that increase by time, since material and properties are inseparable.

Regarding claim 23 and 24, providing the sustained release formulation as layers (claim 32), and coating the outer surface of the lumen with the sustained release material (claim 24), such limitations do not impart patentability to the claims, absent evidence to the contrary. One having ordinary skill in the art would have arranged the sustained release materials into layers, or on the outer surface of the tube according to specific intended use, site of implantation, and severity of condition to be treated.

7. Claim 22 rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '399 and US '661 and further in view of US 4,743,255 ('255).

The combined teaching of US '399 and US '661 are discussed in section 6 as set forth in this office action.

However, the references do not teach radiologically detectable marker material as claimed by claim 22.

US '255 teaches intraocular implantable material that can be incorporated with radio-opaque marker material for follow up using simple radiological technique without resorting to complex imaging techniques (col.1, line 64-col.2, line 2).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide implant comprising glaucoma drainage plastic tube having orifices containing sustained release bioerodible formulation comprising caprolactone and active agent as disclosed by the combined teachings of US '399 and US '661, and further add radio-opaque material that can be detected by radiology to the implant as disclosed by US '255 because US '255 teaches that radio-opaque marker material helps follow up using simple radiological technique without resorting to complex imaging techniques, with reasonable expectation of having implant comprising glaucoma drainage plastic tube containing sustained release bioerodible formulation comprising caprolactone and active agent and radio-opaque marker material that helps follow up by simple radiology technique.

Response to Arguments

8. Applicant's arguments with respect to claims 11, 21-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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